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*IFW*  
**PATENT**

Atty. Docket No.  
AR02766USACON2

CN 27777

Date: Aug 31, 2004 By: *[Signature]*  
Lois E. Miller

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Atul D. AYER et al.

Serial No.: 10/661,168

Filed: September 12, 2003

For: THERAPEUTIC COMPOSITIONS AND  
DRUG DELIVERY SYSTEM FOR  
ADMINISTERING A DRUG

Group Art Unit: 1615

Examiner: CHANNAVAJJALA, L.S.

**INFORMATION DISCLOSURE  
STATEMENT**

Honorable Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☐ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the

mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☒ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

☐ Statement in Accordance with §1.97(e) (attached); or

☒ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☐ There are no listed references which are not in the English language.

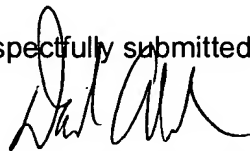
☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750.

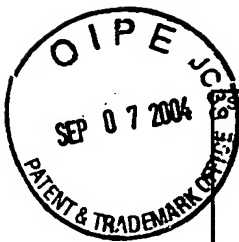
Respectfully submitted,



\_\_\_\_\_  
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Substitute for form 1449A-PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

Application Number	10/661,168
Filing Date	September 12, 2003
First Named Inventor	Atul D. AYER et al.
Group Art Unit	1615
Examiner Name	CHANNAVAJJALA, L.S.
Attorney Docket Number	AR02766USACON2

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	2,799,241		WURSTER	07-16-1957	
	AB	3,133,132		LOEB, et al.	05-12-1964	
	AG	3,173,876		ZOBRIST	03-16-1965	
	AD	3,276,586		ROSAEN	10-04-1966	
	AE	3,541,005		HEINRICH et al.	11-17-1970	
	AF	3,541,006		BIXLER et al.	11-17-1970	
	AG	3,546,876		FOKKER et al.	12-05-1970	
	AH	3,811,444		HELLER et al.	05-21-1974	
	AI	3,845,770		THEEUWES et al.	11-05-1974	
	AJ	3,916,899		THEEUWES et al.	11-04-1975	
	AK	3,962,414		MICHAELS	06-08-1976	
	AL	3,992,518		CHEIN et al.	11-16-1976	
	AM	3,995,632		NAKANO et al.	12-07-1976	
	AN	4,063,064		SAUNDERS et al.	12-13-1977	
	AD	4,066,747		CAPOZZA	01-03-1978	
	AP	4,070,347		SCHMITT	01-24-1978	
	AD	4,079,038		CHOI et al.	03-14-1978	
	AR	4,083,949		BENEDIKT	04-11-1978	
	AS	4,088,864		THEEUWES et al.	05-09-1978	
	AT	4,093,709		CHOI et al.	06-06-1978	
	AU	4,111,202		THEEUWES	09-05-1978	
	AV	4,111,203		THEEUWES	09-05-1978	
	AW	4,160,020		AYER et al.	07-03-1979	
	AX	4,200,098		AYER et al.	04-29-1980	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A-PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 3

<b>Application Number</b>	10/661,168
<b>Filing Date</b>	September 12, 2003
<b>First Named Inventor</b>	Atul D. AYER et al.
<b>Group Art Unit</b>	1615
<b>Examiner Name</b>	CHANNAVAJJALA, L.S.
<b>Attorney Docket Number</b>	AR02766USACON2

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	AY	4,203,439		THEEUWES	05-20-1980	
	AZ	4,285,987		AYER et al.	08-25-1981	
	BA	4,327,725		CORTESE et al.	05-04-1982	
	BB	4,434,153		URQUHART et al.	02-28-1984	
	BC	4,612,008		WONG et al.	09-16-1986	
	BD	7,721,613		URQUHART et al.	01/26/1988	
	BE	4,783,337		WONG et al.	11-08-1988	
	BF	4,816,263		AYER et al.	03-28-1989	
	BG	4,824,675		WONG et al.	04-25-1989	
	BH	4,853,229		THEEUWES	08-01-1989	
	BI	4,863,456		STEPHENS et al.	09-05-1989	
	BJ	4,902,514		BARCLAY et al.	02-20-1990	
	BK	5,082,668		WONG et al.	01-21-1992	
	BL	5,284,662		KOPARKER et al.	02-08-1994	
	BM	5,378,474		MORELLA et al.	01-03-1995	
	BN	5,399,359		BAICHWAL	03-21-1995	
	BO	5,674,895		GUITTARD, et al.	10-07-1997	
	BP	5,837,285		NAKAMACHI et al.	11-17-1998	
	BQ	5,840,754		GUITTARD, et al.	11-24-1998	
	BR	5,912,268		GUITTARD, et al.	06-15-1999	

Examiner Signature		Date Considered	
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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<b>Substitute for form 1449A-PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary) <b>Sheet 3 of 3</b>	<b>Application Number</b>	10/661,168
	<b>Filing Date</b>	September 12, 2003
	<b>First Named Inventor</b>	Atul D. AYER et al.
	<b>Group Art Unit</b>	1615
	<b>Examiner Name</b>	CHANNAVAJJALA, L.S.
	<b>Attorney Docket Number</b>	AR02766USACON2

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published	T <sup>2</sup>
	BS	ABDOU, Hamed M., "Dissolution", <u>Remington's Pharmaceutical Sciences</u> , 17 <sup>th</sup> Ed., Ch. 35, pp. 653-666, 1985.	
	BT	COLEMAN, Michael M. et al., "A practical guide to polymer miscibility", <u>POLYMER</u> , 31:1187-1231, July 1990.	
	BU	FELMEISTER, Alvin, "Powders", <u>Remington's Pharmaceutical Sciences</u> , 14 <sup>th</sup> Ed., Ch. 86, pp 1626-1648, 1970.	
	BV	FINCHER, Julian H., "Particle Size of Drugs and Its Relationship to Absorption and Activity", <u>J Pharm Sci</u> , 57(11):1825-1835, November 1968.	
	BW	GRAFTON, P., "General principles for designing with plastics", <u>Modern Plastics Encyclopedia</u> , 46:62-70, 1969.	
	BX	KING, Robert E, "Tablets, Capsules, and Pills", <u>Remington's Pharmaceutical Sciences</u> , 14 <sup>th</sup> Ed., Ch. 87, pp. 1649-1679, 1970.	
	BY	KING, Robert E. et al., "Oral Solid Dosage Forms", <u>Remington's Pharmaceutical Sciences</u> , 17 <sup>th</sup> Ed., Ch. 90, pp. 1603-1625, 1985.	
	BZ	LEONG, K.W. et al., "Polymeric controlled drug delivery", <u>Adv. Drug Delivery Rev.</u> , 1:199-233, 1987.	
	CA	LINHARDT, Robert J., "Biodegradable Polymers for Controlled Release of Drugs", <u>Controlled Release Drugs: Polymers and Aggregate Systems</u> , Ch. 2, pp. 53-95, 1989.	
	CB	LU, S.M. et al., "Dimensionless presentation for drug release from a coated pure drug bead: 2. Experiment", <u>Int J Pharmaceutics</u> , 112:117-124, 1994.	
	CC	ROFF & SCOTT, <u>Handbook of Common Polymers</u> , 16:164-173, CRC Press., Cleveland Ohio, 1971.	
	CD	<u>The United States Pharmacopeia/The National Formulary</u> USP XXII / NF XVII, <711> Dissolution, pp.1578-1579, 01/01/1990.	
	CE	<u>The United States Pharmacopeia/The National Formulary</u> USP 23 / NF 18, <711> Dissolution, <721> Distilling Range, <724> Drug Release, pp.1791-1796, 01/01/1995.	
	CF	WURSTER, Dale E., "Air-Suspension Technique of Coating Drug Particles", <u>J. Am. Pharm. Assoc</u> , 48(8):451-454, August 1959.	
	CG	WURSTER, Dale E., "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II", <u>J. Am. Pharm. Assoc</u> , 49(2):82-84, February 1960.	

Examiner Signature	Date Considered
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